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Talvey® (active substance: talquetamab)

Temporary authorisation in Switzerland: 30 October 2023

Medicinal product (solution for injection) for the fourth-line treatment of adults with relapsed or refractory multiple myeloma

About the medicinal product

The medicinal product Talvey, containing the active substance talquetamab, is used for the treatment of multiple myeloma ("bone marrow cancer") in adults who have completed at least 3 previous treatment phases, including treatment with drugs in the 3 standard therapeutic classes, and who have demonstrated disease progression after the last treatment phase.

Multiple myeloma (MM) is a rare form of cancer that accounts for around 1-2% of all cancers. The frequency of new cases of MM increases with age. Two thirds of new sufferers are aged over 65. The disease is characterised by excessive replication of plasma cells, which are a type of white blood cell responsible for producing antibodies in the body's defence system (immune system). In MM, the plasma cells multiply in an uncontrolled way in the bone marrow and occasionally in other organs as well. This prevents the normal formation of blood cells and can destroy, or disrupt the function of, bones and other organs.

Since multiple myeloma is a rare, life-threatening disease, the medicinal product has been authorised as an orphan drug. The term orphan drug is used to refer to important medicines for rare diseases.

Talvey was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Israel (MOH), Canada (HC), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are represented in Project Orbis.

Mode of action

Talquetamab, the active substance in Talvey, is an antibody (an immunologically active protein) that binds both to the tumour cell via the GPRC5D antigen and to the CD3 receptor (binding site) on the T cells (cells of the immune system). As a result, talquetamab links the tumour cells with the

T cells, in turn activating the T cells, which are then able to kill the multiple myeloma cells.

Administration

Talvey, containing the active substance talquetamab, is a prescription-only medicine.

Talvey is available as a solution for injection in a vial containing either the 3 mg dose dissolved in 1.5 mL or the 40 mg dose dissolved in 1 mL. Talvey is injected under the skin, and the dosage is increased gradually up to the treatment dose.

Talvey should be administered only under the supervision of a healthcare professional with experience in the intensive care treatment of the potential side effects. At the start of treatment with Talvey, and also at a later stage of the treatment if necessary, inpatient monitoring is needed for at least 48 hours after administration.

Efficacy

The efficacy of Talvey was investigated in an open-label study[1] (MonumentTAL-1) without a control arm with 265 MM patients. The adult patients had already undergone at least 3 previous treatment phases, including treatment with drugs in the 3 standard treatment classes.

Historically, patients with recurrent or treatment-resistant MM who have already received treatment with the 3 standard classes of drugs have had a poor prognosis. According to historic data, the objective responsive rate (ORR)[2] was approx. 30%. The median[3] progression-free survival (PFS)[4] was approx. 3 to 6 months and overall survival (OS) approx. 6 to 12 months.

Of the 122 patients in the study in the patient group treated with 0.4 mg/kg Talvey weekly, 89 achieved a response, which thus corresponds to an ORR of 73%. The median PFS was 7.0 months. As complete data were not yet available at the time of temporary authorisation, the overall survival cannot currently be estimated.

Data from other patient groups in the study support these results.

Precautions, undesirable effects, & risks

Talvey must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent adverse effects (affecting more than 1 in 10 users) are cytokine release

[1] Open-label study: In an open-label (unblinded) study, both the healthcare professionals and the patients know which treatment the study participants are receiving.

[2] ORR (objective response rate) is defined as the percentage of patients who respond to the treatment.

[3] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

[4] PFS (progression-free survival): period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

syndrome (CRS)[5], taste disturbances, hypogammaglobulinemia[6], nail disorders, muscle pain, neutropenia and lymphopenia (low levels of certain types of white blood cell), skin disorders or rashes, fatigue, weight loss, anaemia, dry mouth, fever, dry skin, thrombocytopenia (low levels of blood platelets), difficulty swallowing, diarrhoea, upper respiratory tract infections, pruritus (itching), cough, pain, decreased appetite and headache.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Patients with recurrent or treatment-resistant and heavily pretreated MM have a poor prognosis. There is a considerable need for new therapeutic options.

The data from the submitted study showed a high response rate for Talvey compared to the historical data. The significance of the results for survival is limited, since the duration of the study was not long enough at the time of the data analysis.

The medicinal product Talvey was therefore authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Talvey®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.

[5] Cytokine release syndrome is a systemic inflammatory response to the excess secretion of cytokines (proteins), which activate the white blood cells.

[6] Hypogammaglobulinemia: Disease of the immune system (body's defence system) in which there are too few or no immunoglobulins in the blood. Immunoglobulins are proteins that support the immune system.